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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,214

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Kaoru Hirai

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EXAMINER

WOOD, AMANDA P

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,214	Applicant(s) HIRAI, KAORU	
	Examiner AMANDA P. WOOD	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/06, 10/07, 9/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-17, in the reply filed on 15 July 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election of FAOD enzymes specific for both a glycosylated amino group of an amino acid residue and a glycosylated side chain of an amino acid residue; a glycosylated protein as the glycosylated amine as an analyte; and nonionic surfactants is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 18-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 July 2008.

Claims 1-17 are pending and are presented for consideration on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12 July 2006, 15 October 2007, and 18 September 2008 have been considered by the examiner. An initialed and signed and dated copy of each is included with this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 8-13, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Arkray, Inc. (WO 2003/033729). A copy of the English machine-translation is provided, as well as the corresponding European Application, EP 1443115A1. For page numbers and paragraph numbers, the EP application was used for reference, since these were not available in the machine translation.

A method is claimed of measuring a glycated amine.

Arkray teaches a method for pre-treating a sample in which an analyte glycated amine is to be measured, wherein a degradation FAOD (i.e., fructosyl amino acid oxidase) is added to a sample to act on the non-analyte glycated amino acid or glycated peptide and then a protease is added to degrade the glycated amine prior to adding a second FAOD to cause a redo reaction (see, for example, page 3, paragraphs [009-0015] and page 4, paragraphs [0016-0023]).

Therefore the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arkray, cited above, in view of Komori et al (US 2002/0025546 A1).

A method is claimed of measuring a glycosylated amine.

Arkray teaches a method for pre-treating a sample in which an analyte glycosylated amine is to be measured, wherein a degradation FAOD (i.e., fructosyl amino acid oxidase) is added to a sample to act on the non-analyte glycosylated amino acid or glycosylated peptide and then a protease is added to degrade the glycosylated amine prior to adding a second FAOD to cause a redox reaction (see, for example, page 3, paragraphs [009-0015] and page 4, paragraphs [0016-0023]).

Arkray does not expressly teach a method wherein the degradation step, the step of causing the redox reaction and the step of measuring the redox reaction are performed at the same time.

Komori et al beneficially teach a method wherein a protease treatment, FAOD treatment, and peroxidase oxidation-reduction treatment may be performed simultaneously in methods for measuring glycosylated proteins in blood. Furthermore, Komori et al describe a method of adding tetrazolium compounds in the methods for measuring glycosylated proteins in blood (see, for example, Abstract, and paragraphs [0002-0004, 0007-0015, and 0019-0028]).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Arkray based upon the beneficial teachings provided by Komori et al, with respect to performing simultaneously the steps of protease treatment, FAOD treatment and POD oxidation-reduction treatment as discussed above. Performing such steps simultaneously, as taught by Komori et al, would simplify the method taught by Arkray, and therefore, it would have been both obvious and beneficial for the skilled artisan to measure glycated amines using the combination of the methods taught by Arkray and Komori et al. The result-effective adjustment of particular conventional working conditions (e.g., measuring a particular glycated amine and/or using a particular surfactant) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Conclusion

Art Unit: 1657

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA P. WOOD whose telephone number is (571)272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW
Examiner
Art Unit 1657

/Lisa J. Hobbs/
Primary Examiner, Art Unit 1657